

MAR 16 2001

K002254

Safety and Effectiveness Information

Submitted By: April Lavender, RAC
Vice President, Regulatory Affairs
COOK INCORPORATED
925 South Curry Pike
P.O. Box 489
Bloomington, In 47402
(812) 339-2235

Device: Trade Name: Cook® Pressure Monitoring Catheter
Proposed Classification Name: Diagnostic Intravascular Catheter

Predicate Devices or

Legally Marketed Devices: Cook® Pressure Monitoring Catheter
Marketed & Distributed by
COOK INCORPORATED

Device Description

The Cook® Pressure Monitoring Catheter consists of a kink-resistant tubing that is insert molded to a winged female Luer lock adapter. An inner dilator is inserted through the catheter lumen and is connected to the Luer lock adapter of the catheter. The Cook Pressure Monitoring Catheter is available in 3.0 and 4.0 Fr diameter and in lengths up to 7.5 cm. The device is placed using the Seldinger technique with compatible wire guides and vascular access needles.

Indications for Use

The Cook® Pressure Monitoring Catheter is used for arterial pressure monitoring and blood sampling. It is provided sterile in peel-open packages and intended for one-time use.

Substantial Equivalence

The Cook® Pressure Monitoring Catheter is similar in design and usage to other Cook Pre-Amendment Pressure Monitoring Catheters. There are also numerous intravascular catheters manufactured and marketed with similar indications for use and materials. Among them are the Angiocath Autoguard and Insyte Autoguard manufactured and marketed by Becton Dickinson, the Terumo Surflo Flex I.V. and Terumo Surflash I.V. catheters manufactured and marketed by Terumo Medical Corporation, and the Pathfinder II Angiographic Catheter, manufactured and marketed by Maxxim Medical. The similar indications for use and technological characteristics of the Cook® Pressure Monitoring

510(k) Premarket Notification
Cook® Pressure Monitoring Catheter
COOK INCORPORATED

Catheter as compared to the predicate devices support a determination of substantial equivalency.

Test Data

The Cook® Pressure Monitoring Catheter was subjected to the following tests to assure reliable design and performance under the specified testing parameters. These tests include:

- ◆ Flow Test
- ◆ Kink Resistance Test
- ◆ Tensile Test
- ◆ Biocompatibility

The results of these tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its use as a pressure monitoring catheter.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 16 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. April Lavender, RAC
Vice President, Regulatory Affairs
COOK, Incorporated
925 South Curry Pike
P.O. Box 489
Bloomington, IN 47402

Re: K002254
Trade Name: Cook® Pressure Monitoring Catheter
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: January 11, 2001
Received: January 12, 2001

Dear Ms. Lavender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

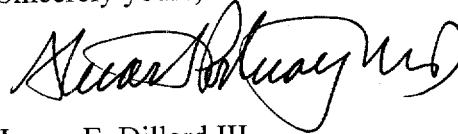
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Premarket Notification
Cook® Pressure Monitoring Catheter
COOK INCORPORATED

510(k) Number (if known):

Device Name: Cook® Pressure Monitoring Catheter

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____


Division of Cardiovascular & Respiratory Devices
510(k) Number K002254